PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Brian R. Reynolds et al.	Confirmation No.: 1188
Serial No.:	10/699,051	Examiner: J. Hoekstra
Filing Date:	October 30, 2003	Group Art Unit: 3736
Docket No.:	1001.1716101	Customer No.: 28075
For:	GUIDEWIRE HAVING AN EMBEDDED MATRIX POLYMER	

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

CERTIFICATE FOR ELECTRONIC TRANSMISSION:
The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 12th day of January 2007.

By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

Brian R. Reynolds et al.

By their Attorney,

Date: 1/12/07

David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

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By Kathleen L. Boekley
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Dear Sir:

Applicants have carefully reviewed the Final Office Action of August 14, 2006 and the Advisory Actions of October 25, 2006 and November 29, 2006. Claims 1-12, 21 and 22 are pending and have been twice rejected. Applicants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 1-12, 21 and 22 were rejected as anticipated by both Rasmussen (EP 0 720 838) and Burnham (U.S. Patent No. 4,764,324). After careful review, Appellants respectfully disagree because neither reference teaches every claim element, as required for anticipation.

For example, claim 1 is not anticipated by Rasmussen for at least the reasons that claim 1 recites "wherein the coil is wound under tension" and "heating the jacket so that the coil tension is relieved," elements that Rasmussen does not teach. With regard to "wound under tension," the Examiner cites a section of Rasmussen that teaches "the [coil] wire may be wound at or pulled axially to a larger pitch." Nothing in this suggests that the wire is wound under tension; the language is directed to altering the pitch of this region of coil and not to subjecting it to winding tension. With regard to "heating the jacket," the Examiner cites several sections, for example,

column 3, lines 16-52 and column 8, line 46 through column 9, line 5. Much of this is inapplicable. Rasmussen discloses two methods of attaching a coil to the core: adhesive and solder. As solder cannot be construed to be a polymer jacket, the portions that deal with solder cannot be used to show anticipation. One portion of the cited sections talks about curing an adhesive with UV radiation (column 9, lines 3-5). However, UV curing is not heating. Heating is raising the temperature. UV curing applies energy in the form of UV radiation but does not inherently or necessarily raise the temperature. The energy of the UV radiation, instead, is used to form molecular bonds. (UV curing is often used in temperature-sensitive applications, where heating would have an unwanted effect. See also the other reference applied, Burnham, at column 10, lines 18-25 for a method of manufacture which depends on UV curing being distinct from heating.) Thus, Rasmussen does not disclose a step of heating a polymer jacket. Further, claim 1 recites "so that the coil tension is removed." There are two possible ways to relieve tension in a coil, annealing to relieve the tension internally and positional change to relieve the tension by eliminating its source. Annealing is done by heating the metal to a certain temperature for a certain period of time, typically measured in hours. There is no suggestion of such a procedure. Likewise, once the coil of Rasmussen is wound onto the core section, there is no positional change. As one can see in comparing Figures 3 and 4, the difference between the figures is in the adhesive 25 and not in the radial or axial position of the turns 11 of the coil. Without either annealing or positional change there can be no removing of coil tension. Thus not only is there no heating of the jacket, there is no heating of the jacket to relieve tension.

With regard to claim 2, which recites "wherein the polymer jacket includes a thermoplastic material," the adhesives discussed in column 8, line 56 through column 9, line 5 are the only polymers that are positioned so that they might be considered the "polymer jacket" of the claim. None of these, so far as Appellants can tell, are thermoplastics. They are all thermosets, a category of polymers that is distinct from thermoplastics. Briefly, thermoplastics soften when heated, while thermosets harden when heated. Thus Rasmussen does not disclose a polymer jacket including a thermoplastic material, as claimed.

With regard to claim 3, which recite "winding a coil that includes a fluorocarbon material," Rasmussen does not disclose any coils that are non-metallic or have any non-metallic components. The Examiner cites column 8, lines 6-16 which teaches a PTFE layer on a body segment 5 of the guidewire. Body segment 5 is proximal of section 6 to which the guidewire is

mounted and therefore cannot even anticipate the polymer jacket of the claim, still less the coil that include a fluorocarbon material. The Examiner also cites column 10, lines 27-41, which talks about the core and about a separate embolization coil which can be releasably threaded onto the guidewire of Rasmussen; this material is completely inapplicable to a claim dealing with a coil that includes a fluorocarbon material and includes the limitations of claim 1 as well. The Examiner also cites the Dymax adhesives of column 9, lines 1-5. The Examiner asserts that these adhesives are fluorescing. Appellants were unable to learn whether this is true, but do know that these adhesives are urethane acrylate adhesives and consequently are not fluorocarbon materials. Whether a material fluoresces is unrelated to whether is contains fluorocarbons.

With regard to claim 7, which recites "so that the outer surface of the jacket wicks between adjacent windings of the coil," Rasmussen discloses a capillary action that works between the turns of the coil and the core wire so that the surface between the turns "has a U-shaped course, which promotes the easy threading in and out of the embolization coil." (Column 8, lines 47-56.) This, of course, is very nearly opposite of wicking between adjacent windings of the coils, where the capillary action is between the adjacent windings of the coils to draw up material from the polymer jacket.

Turning now to Burnham, claim 1 recites "providing a core member having a proximal region and a distal region." Burnham discloses no such member. The core member claimed has a proximal region and a distal region. "Proximal" and "distal" are words of direction that are used and understood with regard to anatomy and with regard to medical instruments that are used internally, but, so far as Appellants are aware, are used in no other situations. Just as no one would talk of (and no one would understand what was meant by) the proximal end of a table saw, no one would talk of the proximal end of a tool. Words of direction are not universally applicable. For example, a piece of paper does not have a sternward region anymore than a cookie has a clockwise portion; the words simply are not applicable. When a person of ordinary skill in the art reads "A method for manufacturing a medical device, comprising the steps of: providing a core member having a proximal region and a distal region," that person would understand the core member to be a part of that medical device for at least the reason that the core member is recited as having a proximal portion and a distal portion; portions which only exist in medical devices and in anatomy. That person would not reasonably understand that core member to be a part of the tooling. Burnham discloses a method of making a catheter which

uses a mandrel 34. The catheter (the medical device) is slid off from the mandrel during the manufacturing process and the mandrel is not part of the medical device. The mandrel, therefore, does not have a proximal region or a distal region as those words of direction are nonsense when applied to tools. It can therefore be seen that Burnham does not disclose at least this element of claim 1.

With regard to claim 3, which recites "wherein the coil includes a fluorocarbon material," the Examiner cites "the radio-opaque dye surrounding the coil as in column 1 lines 45-64." In this passage, Burnham discusses prior art catheters that may be used for fluoroscopy and to deliver radiopaque dyes. This passage deals with methods of use and not with methods of manufacture and is inapplicable for at least that reason. In any case, even if the coil is bathed in dye, it is evident that the coil still would not include the dye. Further, the Examiner has evidently conflated fluoroscopy with fluorocarbons. There is nothing in this passage or in the knowledge generally available to one of skill in this art area to suppose that radio-opaque dyes or fluorescing dyes inherently or even ordinarily include fluorocarbons.

With regard to claim 4, which recites "wherein the coil includes an outer coating and wherein the step of winding a coil...includes winding a coil that includes an outer coating," Burnham does not disclose a coil that includes an outer coating. It appears from the Final Office Action that the Examiner must be interpreting outer coating to include layers that may be disposed over the wound coils as a whole, such as layer 234 of Figure 6 of the present application. However, the language of this claims requires the coil that is wound to include the outer coating, which is to say that the outer coating is an outer coating of the coil (such as coating 24 shown in Figure 1) and not of the guidewire. One could not wind a coil including a layer 234 because such a layer cannot be disposed on the coil until after it is wound. One must therefore interpret the outer coating as being a coating of the coil. Burnham does not disclose any coils having outer coatings.

With regard to claim 22, which recites "disposing a coating over the distal section of the jacket," the Examiner cites the sizing/smoothing step 44. However this manufacturing step is not a coating nor is any material added during this step. Indeed, the material that is sized and smoothed is the material of the jacket. It appears therefore that the Examiner is asserting that an element of Burnham is disposed over itself, which is nonsensical. Burnham teaches that "the protruding portions 46 may be smoothed over in a sizing and/or smoothing step 44...More

significantly, such a step avoids the application of a second extrusion." Column 8, lines 61-68. No one of skill in the art would understand the step of disposing a coating over the distal section of the jacket to include processes where no material was in fact disposed over the distal end of the jacket.

The space constraints of this pre-appeal brief format prevent Appellants from applying the foregoing arguments to each claim to which they may be applied. For example, the arguments regard the "core member" of claim 1 may be applied to every claim. However, appellants respectfully submit that the foregoing show why the cited prior art references do not anticipate the claimed invention and consequently request favorable consideration.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. It is respectfully submitted that all pending claims are in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Brian R. Reynolds et al.

By their attorney,

Date: 1/12/07

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